

Docket No. END-897 DIV2

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicants : Seth A. Forester et al.

Serial No. : 10/734, 671

Art Unit: Not Assigned

**RECEIVED  
CENTRAL FAX CENTER**

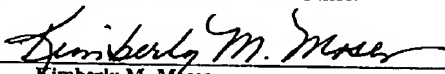
Filed : December 12, 2003

Examiner: Not Assigned

JUL 20 2004

For : METHODS AND DEVICES FOR DEFINING  
AND MARKING TISSUE

I hereby certify that this correspondence is being facsimile transmitted to the  
United States Patent And Trademarks Office.

  
Kimberly M. Moses Date 7/20/04

**OFFICIAL**

Assistant Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**INFORMATION DISCLOSURE STATEMENT**

Dear Sir:

Pursuant to 37 C.F.R. §1.56 and in accordance with 37 C.F.R. §§1.97-1.98, information relating to the above-identified application is hereby disclosed. Inclusion of information in this statement is not to be construed as an admission that this information is material as that term is defined in 37 C.F.R. §1.56(b).

Applicant(s) reserve(s) the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist.

[ X ] In accordance with §1.97(b), since this Information Disclosure Statement is being filed either within three months of the filing date of the above-identified national application (other than a continued prosecution application under §1.53(d)), within three months of the date of entry into the national stage of the above identified application as set

forth in §1.491, or before the mailing date of a first Office Action on the merits of the above-identified application, or before the mailing date of a first Office Action after the filing of a request for continued examination under §1.114, no additional fee is required.

☐ In accordance with §1.129(a), this Information Disclosure Statement is being filed in connection with ☐ the first or ☐ second After Final Submission, therefore:

☐ Statement in Accordance with §1.97(e) (attached); or

☐ Please charge Deposit Account No. 10-0750/END-897DIV2/GSG the fee of \$180.00 as set forth in §1.17(p).

☐ In accordance with §1.97(c), this Information Disclosure Statement is being filed after the period set forth in §1.97(b) above but before the mailing date of either a Final Action under §1.113 or a Notice of Allowance under §1.311, or an action that otherwise closes prosecution and that it is accompanied by one of:

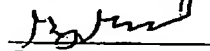
☐ Statement in Accordance with §1.97(e) (attached); or

☐ Please charge Deposit Account No. 10-0750/END-897DIV2/GSG the fee of \$180.00 as set forth in §1.17(p).

☒ Copies of references listed on the attached Form PTO-1449 are not included under 37CFR 1.98(d) where the references have been cited in US Patent Application 09/776,125 to which the application claims priority.

Please charge any deficiency or credit any overpayment to Deposit Account No. 10-0750/GSG/END-897 DIV2.

Respectfully submitted,



Gerry S. Gressel  
Reg. No. 34,342  
Attorney for Applicants

Johnson & Johnson  
One Johnson & Johnson Plaza  
New Brunswick, NJ 08933  
Phone (513) 337-3535  
Date: July 22, 2004

PTO/SB/08A (08-00)

Approved for use through 10/31/2002. OMB 0651-0031  
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Substitute for form 1449A/PTO

**SUPPLEMENTAL INFORMATION  
DISCLOSURE  
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet 1 of 2

Application Number	10/734,671
Filing Date	December 12, 2003
First Named Inventor	Seth A. Foerster et al.
Group Art Unit	Not Assigned
Examiner Name	Not Assigned
Attorney Docket Number	END-897 DIV2

**U.S. PATENT DOCUMENTS**

Examiner Initials	Cite No. <sup>1</sup>	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document mm-dd-yyyy	Pages, Columns, Lines, where relevant passages or relevant figures appear
		Number	Kind Code <sup>2</sup> (if known)			
		3,592,185		Ephraim, et al.	07-13-1971	ALL
		4,087,791		Lemberger	05-02-1978	ALL
		4,541,438		Parker, et al.	09-17-1985	ALL
		4,735,210		Goldenberg	04-05-1988	ALL
		4,735,796		Gordon	04-05-1988	ALL
		5,041,826		Milheiser	08-20-1991	ALL
		5,101,827		Goldenberg	04-07-1992	ALL
		5,114,703		Wolf, et al.	05-19-1992	ALL
		5,127,916		Spencer, et al.	07-07-1992	ALL
		5,300,120		Knapp, et al.	04-05-1994	ALL
		5,433,751		Christel, et al.	07-18-1995	ALL
		5,437,279		Gray	08-01-1995	ALL
		5,470,308		Edwards, et al.	11-28-1995	ALL
		5,482,040		Martin, Jr.	01-09-1996	ALL
		5,496,536		Wolf	03-05-1996	ALL
		5,514,379		Weissleder, et al.	05-07-1996	ALL
		5,555,885		Chance	09-17-1996	ALL
		5,579,766		Gray	12-03-1996	ALL
		5,582,172		Papisov, et al.	12-10-1996	ALL

**FOREIGN PATENT DOCUMENTS**

Examiner Initials	Cite No. <sup>1</sup>	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document mm-dd-yyyy	Pages, Columns, Lines, where relevant passages or relevant figures appear	T <sup>3</sup>
		Office <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup>				
		WO	98/09247	A1	Cothren, et al.	03-05-1998	ALL	
		WO	98/52617	A2	McIntire, et al.	11-26-1998	ALL	

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number. <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 18 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U. S. Patent and Trademark Office, Washington, DC 20231.

DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

PTO/SB/08A (08-00)

Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE  
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Substitute for form 1449A/PTO

**SUPPLEMENTAL INFORMATION  
DISCLOSURE  
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet 2 of 2

Application Number	10/734,671
Filing Date	December 12, 2003
First Named Inventor	Seth A. Foerster et al.
Group Art Unit	Not Assigned
Examiner Name	Not Assigned
Attorney Docket Number	END-897 DJV2

**U.S. PATENT DOCUMENTS**

Examiner Initials	Cite No. <sup>1</sup>	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document mm-dd-yyyy	Pages, Columns, Lines, where relevant passages or relevant figures appear
		Number	Kind Code <sup>2</sup> (if known)			
		5,595,177		Mena, et al.	01-21-1997	ALL
		5,674,288		Knapp, et al.	10-07-1997	ALL
		5,697,902		Goldenberg	12-16-1997	ALL
		5,716,407		Knapp, et al.	02-10-1998	ALL
		5,725,578		Knapp, et al.	03-10-1998	ALL
		5,732,704		Thurston, et al.	03-31-1998	ALL
		5,776,093		Goldenberg	07-07-1998	ALL
		5,776,094		Goldenberg	07-07-1998	ALL
		5,803,913		Khalkhali, et al.	09-08-1998	ALL
		5,810,806		Ritchart, et al.	09-22-1998	ALL
		5,855,609		Knapp	01-05-1999	ALL
		5,857,463		Thurston, et al.	01-12-1999	ALL
		5,868,778		Gershony, et al.	02-09-1999	ALL
		5,895,640		Khalkhali	04-20-1999	ALL
		5,899,865		Chance	05-04-1999	ALL
		5,913,857		Ritchart, et al.	06-22-1999	ALL
		5,970,986		Bolz, et al.	10-26-1999	ALL
		5,977,431		Knapp, et al.	11-02-1999	ALL

**FOREIGN PATENT DOCUMENTS**

Examiner Initials	Cite No. <sup>1</sup>	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document mm-dd-yyyy	Pages, Columns, Lines, where relevant passages or relevant figures appear	T <sup>3</sup>
		Office <sup>4</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup>				
		WO	99/25248	A1	Carroll	05-27-1999		
		WO	99/46284	A2	Rajotte, et al.	09-16-1999		

Examiner Signature		Date Considered	
-----------------------	--	--------------------	--

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number. <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U. S. Patent and Trademark Office, Washington, DC 20231.

DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

PTO/SB/08A (03-00)

Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Substitute for form 1449A/PTO  INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)	Application Number	10/734,671
	Filing Date	December 12, 2003
	First Named Inventor	Seth A. Foerster et al.
	Group Art Unit	Not Assigned
	Examiner Name	Not Assigned
	Attorney Docket Number	END -897 DIV2

Sheet 1 of 3

## U.S. PATENT DOCUMENTS

Examiner Initials	Cite No. <sup>1</sup>	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document mm-dd-yyyy	Pages, Columns, Lines, where relevant passages or relevant figures appear
		Kind Code	Number (if known)			
		Re. 35,391		Brauman	12-03-1996	ALL
		3,194,239		Sullivan	01-16-1963	ALL
		4,298,998		Naficy	11-10-1981	ALL
		4,347,234		Wahlig et al.	08-31-1982	ALL
		4,365,572		Gullemin et al.	11-02-1982	ALL
		4,511,653		Play et al.	04-16-1985	ALL
		4,703,108		Silver et al.	10/27/1987	ALL
		5,061,281		Mares et al.	10-29-1991	ALL
		5,085,629		Golberg et al.	02-04-1992	ALL
		5,120,802		Mares et al.	06-09-1992	ALL
		5,127,916		Spencer et al.	07-07-1992	ALL
		5,192,300		Fowler	03-19-1993	ALL
		5,195,988		Haaga	03-23-1993	ALL
		5,274,074		Tang et al.	12-28-1993	ALL
		5,433,751		Christel et al.	07-18-1995	ALL
		5,470,308		Edwards et al.	11-28-1995	ALL
		5,514,379		Weissleder et al.	05-07-1996	ALL
		5,522,896		Prescott	06-04-1996	ALL
		5,824,081		Knapp et al.	10-20-1998	ALL
		5,869,080		McGregor et al.	02-09-1999	ALL
		5,922,024		Janzen et al.	07-13-1999	ALL
		6,066,325		Wallace et al.	05-23-2000	ALL
		6,214,045	B1	Corbitt, Jr. et al.	04-10-2001	ALL
		2004/0024304	A1	Foerster et al.	02-05-2004	ALL
		2001/0034528	A1	Foerster et al.	10-25-2001	ALL
Examiner Signature					Date Considered	

PTO/SB/08A (08-00)

Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no person is required to respond to a collection of information unless it displays a valid OMB control number.

Substitute for form 1449A/PTO  INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)	<b>Application Number</b>	10/734,671
	<b>Filing Date</b>	December 12, 2003
	<b>First Named Inventor</b>	Seth A. Foerster et al.
	<b>Group Art Unit</b>	Not Assigned
	<b>Examiner Name</b>	Not Assigned
	<b>Attorney Docket Number</b>	END-897 DIV2

Sheet 2 of 3

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS			
Examiner's Initials*	Cite No.	Include name of the author (in CAPITOL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T <sup>2</sup>
		WANG HOM-LAY et al. "Evaluation of an Absorbable Collagen Membrane in Treating Class II Furcation Defects"; pp 1029-1036. November 1994.	
		BROPHY M. REGINA et al. "Biodegradable Polyester Polymers as Drug Carriers". Pp 1-25.	
		SWARBRICK JAMES and BOYLAN JAMES. "Bioabsorbable Polymers." The Encyclopedia of Pharmaceutical Technology. Vol. 1. Absorption of Drugs to Bioavailability of Drugs and Bioequivalence. New York and Basel. Pp 465-476.	
		PARK, KINAM; SHALABY, WALEED AND PARK HAESUN. "Biodegradable Hydrogels for Drug Delivery." Purdue University School of Pharmacy. Pp. 13-19.	
		TSCHAKALOFF A. et al. "Degradation Kinetics of Biodegradable implants depending on the site of implantation." Int. Journal of Oral & Maxillofacial Surgery. 1994. Pp. 443-445.	
		VERT, MICHEL. MAUDUIT, JACQUES AND LI, SUMING. "Biodegradation of PLA/GA Polymers increasing complexity." Biomaterials 1994 Vol. 15, No. 15. Pp. 1209-1213.	
		HOFFMAN, G.O. "Biodegradable Implants in Traumatology A Review on the State-of-the Art." Arch Cathop Trauma Surgery. 1995 Pp. 114: 123-132.	
		BOSTMAN, O. AND PIHLAJAMAKI, H. "Clinical Biocompatibility of Biodegradable Orthopaedic Implants for Internal Fixation." Biomaterials 21 (2000) Pp. 2615-2621.	
		ALONSO, MARIA J., GUPTA, RAJESH K. et al. "Biodegradable Microspheres as Controlled-Release Tetanus Toxoid Delivery Systems." Vaccine 1994 Vol. 12 No. 4. Pp. 299-304.	
		AN, YUEHUEI H., WOOLF, SHANE K., FRIEDMAN, RICHARD. "Pre-clinical In Vivo Evaluation of Orthopaedic Bioabsorbable Devices." Biomaterials 21 (2000) Pp. 2635-2652.	
		MOONEY, D.J. et al. "Transplantation of Hepatocytes Using Porous, Biodegradable Sponges." Transplantation Proceedings, Vol. 26, No. 6 Dec. 1994 Pp 3425-3426.	
		CUTRIGHT, DUANE E. et al. "Degradation Rates of Polymers and Copolymers of Polylactic and Polyglycolic Acids." U.S. Army Institute of Dental Research, Walter Reed Army Medical Center, Washington, D. C. Pp. 142-151.	
		KULKARNI, R. K. PHD. Et al.; "Polylactic Acid for Surgical Implants." Arch Surgery. Vol. 93, Nov. 1966 Pp. 839-843.	
		KULKARNI, R. K. PHD. Et al.; "Biodegradable Poly(lactic acid) Polymers." U.S. Army Institute of Dental Research, Walter Reed Army Medical Center, Washington, D. C. (1971) Vol. 5. Pp. 169-181.	
		CHASIN, MARK AND LANGER, ROBERT. - LEWIS, DANNY H. "Biodegradable Polymers as Drug Delivery Systems." Controlled Release of Bioactive Agents from Lactide/Glycolide Polymers Ch. 1 Pp -41 (1990). And BOGDANSKY, SIMON "Natural Polymers as Drug Delivery Systems." Pp. 231-259.	
		HUANG, SAMUEL J. et al.; "Hydrophilic-Hydrophobic Biodegradable Polymers: Release characteristics of Hydrogen-Bonded, Ring-Containing Polymer Matrices. (1994) Biomaterials (1994, Vol. 15 No. 15 Pp. 1243-1247.	
		BECKER, PAUL L. "Comparison of Antibiotic Release from Polymethylmethacrylate Beads and Sponge Collagen." Journal of Orthopaedic Research. (1994) Vol. 12, No. 5.	
		MACKINNON, SUSAN E. "Clinical Nerve Reconstruction with a Bioabsorbable Polyglycolic Acid Tube." Plastic and Reconstructive Surgery. March 1990.	
		NAKAMURA, T., et al. "New Bioabsorbable Pledgets and Non-Woven Fabrics Made from Polyglycolide (PGA) for Pulmonary Surgery. Clinical Experience." Thoracic Cardiovascular Surgeons. (1990) Pp. 81-85.	
		TONG, XIAO-JIE, et al.; "Sciatic Nerve Regeneration Navigated by Laminin-Fibronectin Double Coated Biodegradable Collagen Grafts in Rats." BRAIN RESEARCH 663 (1994) Pp. 155-162.	
		MATSUSUE, YOSHITAKA, et al.; "In Vitro and In Vivo Studies on Bioabsorbable Ultra-High-Strength Poly (L-Lactide) Rods." Journal of Biomedical Materials Research (1992) Vol. 26, Pp. 1553-1567.	
		HUTMACHER, DIETMAR. "A Review of Material Properties of Biodegradable and Bioresorbable Polymers and Devices for GTR and GBR Applications." The International Journal of Oral & Maxillofacial Implants. (1996) Vol. 11 No 5. Pp. 667-678.	
Examiner Signature		Date Considered	

PTO/SB/88A (08-00)

Approved for use through 10/31/2001. OMB 0651-0001

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Substitute for form 1449A/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> (use as many sheets as necessary)	<b>Application Number</b>	10/734,671
	<b>Filing Date</b>	December 12, 2003
	<b>First Named Inventor</b>	Seth A. Foerster et al.
	<b>Group Art Unit</b>	Not Assigned
	<b>Examiner Name</b>	Not Assigned
	<b>Attorney Docket Number</b>	END-897 DIV2

Sheet 3 of 3

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS			
Examiner's Initials*	Cite No. <sup>†</sup>	Include name of the author (in CAPITOL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T <sup>2</sup>
		PARK, KINAM et al.; "Biodegradable Hydrogels for Drug Delivery." Purdue University, School of Pharmacy. Pp. 2-28	
		CHU, C.C. and DUMITRIU, SEVERIAN <i>Polymeric Biomaterials 2<sup>nd</sup> ed.</i> "Biodegradable Biomaterials Having Nitric Oxide Biological Activity." Ch. 5. Pp 123-124. and ROKKANEN, PENTTI U. "Bioabsorbable Polymers for Medical Applications with an Emphasis on Orthopedic Surgery." Ch. 20 Pp. 545-547.	
		MIDDLETON, John C. and TIPTON, ARTHUR.; "Synthetic Biodegradable Polymers as Medical Devices." (March 1998) Pp. 1-14 of website: <a href="http://www.device-link.com/mpb/archive/98/03/002.html">http://www.device-link.com/mpb/archive/98/03/002.html</a> . 08-28-2002.	
		TSURUTA, TEIJI ; KIMURA, YOSHIBARU Et al. "Biomedical Applications of Polymeric Materials." 1993 Pp. 164-186.	
		PARKER, STEVE H. and KLAUS, ANITA J. "Performing a Breast Biopsy with A Directional, Vacuum-Assisted Biopsy Instrument." <i>From the RSNA Refresher Courses- Continuing Education</i> (1997) Vol. 17 No. 5 pp. 1233-1252.	
		LEONARD, CHARLES MD. Et al. "Use of Ultrasound to Guide Radiation Boost Planning Following Lumpectomy for Carcinoma of The Breast." (Aug. 1993) <i>International Radiation Oncology Biology. Phys.</i> Vol. 27. pp. 1193-1197	
Examiner Signature		Date Considered	